

Technical Update

Risk Assessment Requirements Comparison of the 1996 Guideline and the New Record of Site Condition Regulation (153/04)

The 1996 MOE *"Guideline for Use at Contaminated Sites in Ontario"* (as revised February 1997), (*Guideline*) and associated technical support documents, were created to provide property owners and their consultants with options and guidance for site restoration. One option provided was to conduct site-specific risk assessments (SSRA). SSRAs prepared in accordance with the *Guideline* underwent external peer review and were submitted to the MOE for review. SSRAs, which were determined to have been conducted in accordance with the *Guideline*, were considered complete by MOE and the owners received acknowledgement from MOE.

When to Use the New Regulated Requirements
Transition-related provisions are specified in sections 44 and 45 of the new Record of Site Condition Regulation (O. Reg. 153/04) (RSC Regulation). Additional guidance related to transitioning to the new risk assessment (RA) requirements can be found in the MOE Technical Update entitled "Risk Assessment: Transition Process from the *"Guideline for Use at Contaminated Sites in Ontario"* to the *"Record of Site Condition Regulation"*.

As of October 1, 2004, site specific risk assessments (now simply called RAs) will have to meet requirements of the RSC Regulation. The Environmental

Protection Act, as amended by the Brownfields Statute Law Amendment Act, 2001, provides for the use of RAs for the development of standards to support filing a RSC. The RSC Regulation specifies the form and content of a RA for this purpose.

Other types of RAs (contaminated land or otherwise) are not bound by the RSC Regulation, unless it is specified in a legal instrument that they must meet the RA provisions of the RSC Regulation. Examples of those RAs that are not explicitly bound by the RSC Regulation include:

- a) RAs which result from Ministry orders or other responses or directives by the Ministry to manage community or area-wide contamination issues,
- b) RAs developed for identification/qualification/quantification of threats under Source Protection,
- c) RAs associated with Nutrient Management and other MOE or external processes referred to as risk assessment.

What Are the New Requirements?

RAs must be prepared and submitted in accordance with Schedule C of the RSC Regulation. RA reports must comply with the mandatory requirements specified in Section 4 of Schedule C (Table 1). Many of these requirements are similar to those found in the



Guideline. For example, as was the case under the Guideline, the RSC Regulation requires that RAs include both human health and ecological components and RAs must be completed by a team of experts.

Under the new RSC Regulation, there are several clarifications and changes to the risk assessment process as it existed in the Guideline, including the requirements that RAs be prepared under the supervision of a qualified person (QP) after October 1, 2004. Interim qualifications for the QP and the RA team are set out in the RSC Regulation and will be updated with a certification program under development by the Ministry.

Also there are new requirements for submission of a Pre-Submission form (PSF), as specified in Section 3 of Schedule C, and for mandatory certifications to be made by the QP, as specified in Section 5 of Schedule C.

To facilitate the transition to the RSC Regulation approach, the following tabular comparison of the various components of the Guideline and the RSC Regulation processes has been prepared. Included in the comparative analysis is a brief explanation of the rationale for the change. The RSC Regulation should be consulted for specific requirements that must be met.

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Qualifications to Undertake a Risk Assessment (RA)	<p>Expertise is recommended in the following disciplines:</p> <ol style="list-style-type: none"> 1) toxicology 2) environmental chemistry 3) ecology 4) hydrogeology 5) environmental fate and transport modelling 6) epidemiology and community medicine in some cases. <p>No requirement for submission of qualifications and no attempt was made by MOE to verify the expertise or credentials of the team members.</p>	<p>The Qualified Person (QP) must demonstrate that the RA team has expertise in the following areas:</p> <ol style="list-style-type: none"> 1) human health toxicity 2) ecotoxicity 3) hydrogeology 4) soil science/soil chemistry 5) environmental science 6) environmental chemistry 7) analytical chemistry 8) engineering <p>unless an explanation is provided for omission of a particular discipline.</p> <p>[refer to Table 1 – Section 2, pg 67 of the RSC Regulation]</p> <p>A résumé for the QP and each team technical leads are to be provided</p> <p>As part of the process of submitting the Pre-Submission Form (PSF) form, the QP will self-declare in the PSF the qualifications set out in the regulation by attaching a post secondary education transcript and work references. If qualifications have been previously submitted to the Ministry and accepted via a previous PSF they may not be required again.</p>	<p>To improve the quality of submissions and reduce times required for review and approval by the Ministry</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Pre-Submission Form (PSF)	Not required	<p>A PSF must be submitted to the Ministry for review in advance of the RA report. The PSF provides an opportunity to confirm with the Ministry the risk assessment approach and general scope in both narrative and visual form (conceptual site model)</p> <p>[refer to Schedule C – Section 2 and 3 (pg 57) of the RSC Regulation]</p> <p>MOE will prepare a letter of response to the Pre-Submission Form (PSF) that provides the review timeline required for the RA approach, as well as comments concerning the scope of the RA.</p> <p>The outcome of this preliminary consultation is not binding on the proponent or MOE, as the understanding of site conditions may develop and change during the course of the risk assessment.</p> <p>A separate Technical Update will be made available regarding preparation and submission of a PSF.</p>	<p>This process is designed to reduce the possibility of a RA being conducted at the expense of the property owner that could be rejected after the work is completed. An early indication of the site conditions and proposed RA approach will give owners and other interested parties improved certainty with respect to the outcome of the RA on their property.</p>
External Peer Review	Ministry accepts and reviews SSRA submissions only if the report includes a third-party review as well as the author's responses to the peer reviewer's concerns.	<p>Third-party review will no longer be a pre-requisite to Ministry review of an RA.</p> <p>[refer to Schedule C – Section 3, subsection 1, (pg 57) of the RSC Regulation]</p>	<p>Early interaction with the MOE through the PSF will serve to better align the content of the RA with MOE expectations.</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Notification to Municipality and Public Communication	Proponent is advised to send notification of the SSRA approach to the municipality and to provide an opportunity for public involvement in SSRA process.	<p>Notification of the RA approach to the municipality is optional except where the QP intends to prepare a RA that assumes ground-water under the RA site does not or will not serve as a raw water supply for a drinking water system.</p> <p>Public communication is considered optional for all but one type of RA. The QP is required to provide public communication in situations where the District Office has indicated the site is located in a wider area of abatement.</p> <p>[Refer to Schedule C – Section 10, (pg 66); Table 1 – Section 8 of the RSC Regulation]</p>	Although still considered a desirable feature of any RA, the Regulation mandates municipality notification and public consultation in only specific circumstances.
Submission of Completed RAs to the MOE and Time to Review	<p>SSRAs submitted to the Ministry via District Office and forwarded to Standards Development Branch for review and acknowledgement in the order received.</p> <p>Time to review a RA submission was targeted at 12 weeks, although this varied depending on the quality of both the SSRA submission and the site characterization.</p>	<p>The PSF and Risk Assessment are submitted to MOE via the Application Processing Unit of Environmental Assessment and Approval Branch.</p> <p>Specific time periods have been identified for completion of the review by MOE. The details on how the 'clock' is started and stopped are provided in the Regulation. The time periods range from 8 to 22 weeks, depending on the content and complexity of the RA.</p> <p>[Refer to Section 46 (pg 33) of the RSC Regulation]</p> <p>A subsequent Technical Update will focus on RA Approaches and Timelines.</p>	Specified time frames can now be targeted due to improved quality resulting from the PSF and QP process and the standardization of the report format.

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Site Characterization	<p>Guidance provided on the form and content of Phase I and II Environmental Site Assessments (ESAs), but allowed flexibility to modify if desirable.</p> <p>No limit on how old data used in the SSRA could be.</p> <p>No guidance on how ESA data was to be referenced in SSRAs.</p>	<p>Phase I and II ESAs must now be conducted in accordance with the CSA Standards.</p> <p>The RA must now include a summary of the Phase I and II sampling programs, specifically considering data quality, uncertainty and suitability of the data for use in the risk assessment, and details of any additional sampling undertaken to support the risk assessment.</p> <p>[Refer to Schedule C – Section 4, subsection 6 (pg. 60) of the RSC Regulation]</p> <p>As with the Guideline, these requirements do not prevent the Ministry from requesting additional information or copies of Phase I or II ESAs and/or other relevant site reports that the Ministry deems necessary to review.</p> <p>Site data used in the RA should include (but is not limited to) data collected in the last two years.</p> <p>Selection of appropriate toxicity data used in the RA should consider data from credible agencies published within the last two years.</p>	<p>Designed to improve and accelerate the Ministry's review of RAs where a number of previous ESAs have been conducted and not included in the RA.</p>
Analytical Protocols	<p>Analytical protocols provided in Guideline Support document.</p>	<p>Analytical protocols to be used in analyzing samples collected in support of an RA are referenced in Regulation and now published on the Ministry's web site.</p> <p>[Refer to Section 47 of the RSC Regulation]</p> <p>Protocols have been revised for new site condition standards for petroleum hydrocarbons.</p>	<p>Similar approach as used in the Guideline.</p> <p>Canada Wide Standards have been adopted for petroleum hydrocarbons in soil.</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Groundwater Quality	<p>Designation of groundwater as non-potable, must meet certain requirements; i.e.</p> <p>a) The area is already served by a municipal drinking water supply which does not rely on the local groundwater.</p> <p>b) Present or future surface water or groundwater sources for drinking water, including water for agricultural and/or aquacultural purposes will not be adversely affected.</p> <p>c) The municipality is notified that the SSRA treats groundwater as non-potable.</p>	<p>Requirements for non-potable ground water remain unchanged but are more explicit in the Regulation; i.e.</p> <p>a) The RA property and all other properties located within 100 metres of the boundaries of the property are supplied by a municipal drinking water system as defined in the Safe Drinking Water Act, 2002.</p> <p>b) The municipality has not identified the area as a supply of drinking water and,</p> <p>c) The RSC does not specify agricultural use for the property.</p> <p>[Refer to Schedule C – Section 4, subsection 5 of the RSC Regulation]</p> <p>The QP must notify municipality if the RA assumes that groundwater under the RA property does not serve as a raw water supply for a drinking water system as defined in the Safe Drinking Water Act, 2002 and the municipality's response must be included in the RA.</p> <p>[Refer to Schedule C – Section 4, subsection 5 of the RSC Regulation]</p>	<p>The main difference pertains to the new requirement for clearly determining the acceptability of the proposed non-potable ground water use with responsibility for the supply of safe drinking water to its residents.</p>
Report Format	<p>No specific report format, although guidance provided on the main components of both human health risk assessments (HHRA) and ecological risk assessments (ERA) typically resulted in separate reports being prepared and submitted.</p>	<p>RA process must include both human health and ecological health risk assessment in a single report.</p> <p>Table 1 of Schedule C identifies the report sections and titles that must be included, and provides the option for additional sections if appropriate.</p> <p>[refer to Schedule C – Section 2 (pg 57); Section 4 (pg 60), Table 1 – Section 4 and 5 of the RSC Regulation]</p>	<p>Designed to improve consistency in submissions and reduce the time required for the Ministry to complete the review.</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Contaminants of Concern	The SSRA should assess contaminants of concern (COC) which include chemical parameters for which no generic soil or groundwater criteria are provided in Tables A-E of the <i>Guideline</i>	<p>COCs must include contaminants for which there are exceedances of the site condition standards. At the discretion of the QP, COCs should include chemical parameter(s) for which there is no site condition standard specified in the Soil, Groundwater and Sediment Standards document.</p> <p>[Refer to Schedule C – Table 1 - Section 3 (pg 68) of the RSC Regulation]</p> <p>Where a contaminant is measured and there is no Site Condition Standard, the QP has the option of submitting a New Science Risk Assessment to set a site specific standard or to certify that concentrations left on the property are protective of both human health and the environment without performing a RA.</p> <p>[Refer to Schedule C – Section 5 (pg 67) of the RSC Regulation]</p>	Similar to the existing <i>Guideline</i> . Additional discretion given to the QP. Lack of a published site condition standard does not mean that risk does not have to be assessed.
Conceptual Site Model	The <i>Guideline</i> recommends that both HHRAs and ERAs include a problem formulation section which characterizes potential receptors and relevant exposure pathways for each COC.	<p>For each COC, the following is to be provided:</p> <p>a) A conceptual model is to be provided that shows all potential human and ecological receptors and exposure pathways.</p> <p>b) Each relevant pathway is to be provided, including those that may be eliminated through risk management measures.</p> <p>The conceptual site model (CSM) is expected to highlight the effects of any existing or anticipated pathway barrier on potential exposure pathways.</p> <p>The CSM must therefore distinguish between routes of exposure which would potentially exist without risk management measures (existing or future pathway barriers) and routes which are expected to exist under conditions which include risk management measures.</p> <p>[Refer to Schedule C – Table 1 - Sections 4 and 5 (pg 68 and 71) of the RSC Regulation]</p>	<p>Greater emphasis is placed on the development of the CSM and this is reflected in the requirement for its inclusion in the PSF.</p> <p>The linkage with risk management measures also should facilitate a better understanding of the potential for the Director to issue a Certificate of Property Use (CPU).</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Exposure Analysis	The <i>Guideline</i> requires that the SSRA identify exposure pathways of concern and quantify all potential exposures to receptors	Exposure calculations for each relevant pathway are to be provided, including those that may be eliminated through risk management measures.	In this way, the efficiency of a risk management measure in reducing overall site risk is to be demonstrated
Risk Characterization	SSRAs are considered complete if: a) it demonstrates that a concern to human health and/or the environment is demonstrated to be acceptable at a specific site, or b) site-specific 'effects-based' criteria are determined for risks of concern.	Schedule C requires all RAs to specify a property-specific standard (a numeric value) for each contaminant of potential concern identified in the Phase I or II ESA. [Refer to Table 1 – Section 4 and 5, (pg 70 and 72) of the RSC Regulation]	Required by the Environmental Protection Act (EPA) for filing a RSC.
Risk Management	SSRAs which derive site-specific soil and groundwater criteria by utilizing risk management measures similar to those utilized in the setting of generic criteria are considered to use Level 1 risk management measures. Level 2 risk management includes engineered pathway blockage mechanisms, assumptions which exclude certain receptors and changes to the one-in-a-million lifetime excess cancer risk. A 'Certificate of Prohibition' may be issued on the titles of properties with Level 2 Risk Management.	Risk management is no longer categorized as Level 1 or 2. RAs requiring risk management measures may, at the Director's discretion, have associated with them a control document known as a Certificate of Property Use. The risk management measures will also be reported in the Record of Site Condition (RSC) which is placed on the Environmental Site Registry (ESR) Registration on title of the property may still be required in relation to property restrictions or requirements. [Refer to Schedule C – Sections 4, subsection 6 (pg 61); Table 1 – Section 1 and 7, (pg 67 and 74) of the RSC Regulation]	The QP has more discretion to make recommendations regarding the need for risk management. All risk management is described in the EPA as a component of risk assessment which may result in a CPU at the Director's discretion.

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Risk Management Measures/Plans	<p>SSRAs should include all recommendations concerning risk management measures associated with Level 2 RM.</p> <p>Detailed Risk Management Plans are associated with site remediation phase and are reviewed by the Ministry District Office.</p>	<p>The EPA describes risk management measures as being contained in a RA. A RA that concludes that there is a need for risk management on a property must provide a detailed risk management plan that includes hydrogeological and engineering needs as well as requirements for monitoring, maintenance, replacement and contingency.</p> <p>[Refer to Schedule C – Section 4, subsection (6); Table 1 – Section 7 of the RSC Regulation]</p> <p>Hydrogeology and engineering design must be stamped by a qualified person.</p>	<p>Incorporating all risk management measures in the RA in the form of a risk management plan ensures that the risk management measures are clearly linked to the RA outcome and proposed standards developed/certified by Qualified Persons with appropriate credentials and result in enforceable conditions in a Certificate of Property Use, if one is issued.</p>
Upper Concentration Limits (UCL)	<p>All SSRAs which produce site-specific criteria that exceed the Upper Concentration Limits, as shown in Appendix E of the Guideline are considered to be SSRAs requiring some form of Level 2 risk management.</p>	<p>Upper concentration limits (UCL) no longer apply to site-specific standards derived using the RA approach. Risk management measures may be required based on the QPs responsibility to certify that concentrations left on the property are protective of both human health and the environment.</p> <p>[Refer to Schedule C - Section 5 (pg 61) of the RSC Regulation]</p>	<p>The objective of these changes was to give more discretion to the QP to make recommendations regarding the need for risk management measures and to ensure that any recommendations made are supported by a QP with appropriate credentials.</p>
50% Solubility	<p>If a site-specific groundwater concentration for a given chemical parameter is greater than 50% solubility, the SSRA is considered to require Level 2 risk management and registration on title.</p>	<p>Mandatory risk management is no longer automatic if the groundwater concentration for a given chemical parameter exceeds the 50% solubility concentration.</p> <p>[Refer to Schedule C - Table 1 – Section 6 (pg 74) of the RSC Regulation]</p> <p>Risk management measures may be required, based on a demonstration of the risk of free product formation and the need for mitigation.</p>	<p>The objective of these changes is to give more discretion to the QP to make recommendations regarding the need for risk management measures and to ensure that any recommendations made are supported by a QP with appropriate credentials.</p>

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Off-site Impacts	SSRAs completed in accordance with the <i>Guideline</i> are focused on meeting acceptable effects-based concentrations in soil and groundwater both at and beyond the property boundary.	Under Schedule C, the issue of off-site impacts is further clarified. QPs must assess whether the property-specific standards proposed in the RA have the potential to result in a concentration greater than the applicable full depth site condition standard at the nearest receptor located off-site. [Refer to Schedule C – Section 5, subsection 2 (pg 62); Table 1 – Section 4 and 5 (pg70) of the RSC Regulation]	Regulation supplies minor clarifications as to definition of off-site impacts
Risk Assessment Certifications	No specific certifications were required under the Guideline unless the SSRA involved Level 2 risk management and an RSC was completed. Under these conditions, the lead environmental consultant had to swear an Affidavit and the owner had to make signed declarations.	The QP who conducted the risk assessment must certify, using prescribed language, that the requirements of the EPA and the RSC Regulation have been met and that, in the opinion of the QP, the risk assessment was sufficient to evaluate risks to human and ecological receptors on the site and that the risks are acceptable (as compared to the level of risk intended by the Ministry's full depth generic standards). Where the Qualified Person has indicated in the risk assessment that the standards specified in the risk assessment will not compromise meeting applicable site condition standards off-site, a certified statement must also be that effect. [Refer to Schedule C – Section 5 of the RSC Regulation]	These certifications are consistent with a regulation approach to site assessment and clean-up under the EPA and Reg. 153/04 and underpin the protection that is provided to owners who have filed a RSC in the Registry.

Component	1996 Guideline	Reg. 153/04	Goal/Rationale
Locally Elevated Background	<p>Local background can be determined in areas with naturally elevated concentration, that are unaffected by local point sources of air or land pollution.</p> <p>Estimation of Locally Elevated Background must meet the following conditions;</p> <ol style="list-style-type: none"> 1) local background concentrations in soil/property specific standards do not exceed full depth generic criteria, and 2) local backgrounds concentrations in soil/property specific standards are determined using a method similar to that used for developing Ontario Typical Range values. <p>A minimum of two soil samples must be collected from each of not less than 30 separate sampling sites distributed over at least ten different geographical locations.</p> <p>Sample areas should not be in areas affected by local point sources of air or land pollution.</p>	<p>RAs for "Estimation of Local Background Concentrations" must meet the following requirements:</p> <ol style="list-style-type: none"> 1) local background concentrations in soil/property specific standards do not exceed full depth generic site condition standards, and 2) local backgrounds concentrations in soil/property specific standards are determined using a method similar to that used for developing standards in Table 1 of the Soil, Groundwater and Sediment Standards <p>[Refer to Schedule C – Section 8 (pg 64) of the RSC Regulation]</p> <p>Sampling requirements are the same as was in the Guideline with the following addition:</p> <ol style="list-style-type: none"> 3) A sampling composite within a 2 meter radius should be replicated in one out of ten samples (i.e. 30 sampling sites requires at least 6 composite samples be submitted.) 4) The QP may utilize data collected by another agency provided the Director agrees that the sampling method was equivalent and that the data are consistent with what would have been generated via a sampling program. 	<p>Locally elevated background was always an option for a site specific standard.</p> <p>These values are not published with the RSC Regulation.</p> <p>The derivation of these values is provided as an alternative form of RA.</p>
Record of Site Condition	<p>Owner submits completed Record of Site Condition (RSC) to the Ministry's District Office.</p>	<p>The QP who conducted the ESAs completes an RSC which references the RA standards and, if applicable, the certificate of property use for inclusion in the Environmental Site Registry (ESR).</p> <p>[Refer to Section 3 (pg 39) of the RSC Regulation]</p>	<p>This is consistent with a regulation approach to site assessment and clean-up under the EPA and Reg. 153/04.</p>

SUMMARY OF INTERIM EDUCATION AND EXPERIENCE REQUIREMENTS FOR QUALIFIED PERSONS UNDER REG. 153/04

Interim Qualifications	Combined Total Years Experience in: a) Conducting or Supervising ESAs b) Conducting or Supervising RAs c) Reviewing RAs for a Public Authority	Including a Minimum of No. of Years: a) Conducting/Supervising RAs or b) Reviewing RAs for a Public Authority
Bachelor's degree in science, engineering or applied technology	8	2
Master's degree in science or engineering	7	2
Doctorate degree in science or engineering	5	2

Please note that the definition of ESAs in the above table includes, but is not limited to phase I or II ESAs; and that RAs here includes, but is not limited to, RAs under this regulation and SSRAs under the Guideline [refer to Section 6 (pg10) of the RSC Regulation]

If there are questions or need for further clarification, please make your enquiries to:

Mark Turner
Ontario Ministry of the Environment,
Standards Development Branch,
40 St. Clair Ave West, 2nd floor
Toronto, Ontario M4V 1M2
Tele: 416-327-6949 Main Fax: 416-327-2936